

Hello, and welcome to the Long-Term Care Surveyor Training for the new Staff Vaccination Requirement.

CMS-3415-IFC

- On November 5, 2021, CMS published CMS-3415-IFC entitled, "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination," revising the infection control requirements that most Medicare- and Medicaid-participating Facilities and suppliers must meet to participate in the Medicare and Medicaid programs.
- The rule requires each facility develop and implement policies and procedures to ensure all staff, regardless of clinical responsibility or resident contact, are fully vaccinated for COVID-19.
- The long-term care requirements will be located in the new federal tag F888 and will be implemented in a two-phase approach.

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Key Term

Staff

- Refers to individuals who provide any care, treatment, or other services for the facility and/or its residents.
- Includes facility employees, individuals under contract or arrangement, such as hospice and dialysis staff, therapists, mental health professionals, licensed practitioners, adult students, trainees or volunteers.
- Staff would not include anyone who provides only telehealth or support services outside of the facility and does not have direct contact with residents and other staff
- Facilities are not required to ensure the vaccination of individuals who very infrequently provide ad hoc, non-health care services (such as annual elevator inspection or services performed exclusively off-site).

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One of the key terms we'd like to highlight is "Staff".

Staff Refers to individuals who provide any care, treatment, or other services for the facility and/or its residents.

Includes facility employees, individuals under contract or arrangement, such as hospice and dialysis staff, therapists, mental health professionals, licensed practitioners, adult students, trainees or volunteers.

Staff would not include anyone who provides **only** telehealth or support services outside of the facility and **does not** have direct contact with residents and other staff.

Facilities are not required to ensure the vaccination of individuals who very infrequently provide ad hoc, non-health care services (such as annual elevator inspection or services performed exclusively off-site).

Policies and Procedures Overview

Facilities must have policies and procedures that include processes for ensuring:

- All staff have received at least a single-dose COVID-19 vaccine or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care or services;
- All staff, except those granted an exemption or for whom the vaccine must be temporarily delayed, are fully vaccinated for COVID-19.
- Those staff who are not fully vaccinated adhere to additional precautions in order to mitigate the spread of COVID-19;
- Staff are able to request an exemption from vaccination for medical or non-medical reasons;

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Those staff who are not fully vaccinated adhere to additional precautions in order to mitigate the spread of COVID-19;

Staff are able to request an exemption from vaccination for medical or non-medical reasons;

Policies and Procedures Overview (cont.)

Facilities must have policies and procedures that include processes for:

- Ensuring documentation for medical exemption requests contains all of the necessary information;
- Tracking and securely documenting
 - each staff member's vaccination status, including any booster doses received,
 - staff who have requested and were granted an exemption to vaccination,
 - staff for whom the vaccine must be temporarily delayed; and
- Contingency plans for staff who are not fully vaccinated.

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Policies and Procedures must include processes to ensure documentation for medical exemptions contain all necessary information, and tracks and securely documents the following:

Each staff member's vaccination status, including any boosters received;

Each staff who has requested and been granted an exemption to vaccination; and

Each staff for whom the vaccine must be temporarily delayed.

Policies and Procedures must also include processes for contingency plans for staff who are not fully vaccinated.

Additional Precautions

There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission by staff who have not completed their primary vaccination series, have a pending or granted exemption, or have a temporary delayed vaccination, including, but not limited to:

- · Reassigning staff:
 - to non-patient care areas,
 - to duties that can be performed remotely (i.e., telework), or
 - to duties which limit exposure to those most at risk (e.g., assign to residents who are not immunocompromised, unvaccinated).
- Requiring staff testing at least weekly, regardless of the community level of transmission;

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Additional precautions are intended to mitigate the transmission and spread of COVID-19 by staff who have not completed their primary vaccination series, been granted an exemption, or a temporary delay must adhere to additional precautions. There are a variety of actions or job modifications that can be implemented to reduce the risk of transmission by staff, including but not limited to:

Reassignment to non-patient care areas, duties performed remotely, or assignment to residents who are not immunocompromised or unvaccinated.

Additional precautions may also include testing at least weekly, regardless of community transmission;

Additional Precautions (cont.)

- Requiring staff to follow additional CDC-recommended precautions, even if the facility is located in a county with low to moderate community transmission, such as:
 - · adhering to universal source control, and
 - physical distancing measures in areas that are restricted from resident access (e.g., staff meeting rooms, kitchen).
- Requiring staff to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, whether or not they are in contact with residents.
- Facilities may also consult with their local health department to identify other
 actions that can potentially reduce the risk of COVID-19 transmission by staff who
 are not fully vaccinated.

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Additional Precautions, continued:

Additional Precautions may include: requiring staff to follow CDC recommended precautions such as: universal source control and physical distancing measures while in staff meeting rooms, and or the kitchen.

Requiring use of NIOSH-approved N95 or higher level respirator for source control, at all times.

Facilities may also consult with their local health department for other actions to reduce transmission.

Within 30-days of Issuance of QSO 22-07-All

The facility must implement the following:

- All staff, prior to providing any care or services, must have
 - received the first dose of a multi-dose COVID-19 vaccine, or
 - a one-dose COVID-19 vaccine, or
 - been granted or have a pending request for exemption, or
 - been identified as having a temporary vaccination delay, and
- The facility must have developed and implemented policies and procedures (except 483.80 (i)(3)(ii)).

Within 30 days of issuance of QSO 22-07-All, The facility must implement the following:

All staff, prior to providing any care or services, must have

received the first dose of a multi-dose COVID-19 vaccine, or

a one-dose COVID-19 vaccine, or

been granted or have a pending request for exemption, or

been identified as having a temporary vaccination delay, and

The facility must have developed and implemented policies and procedures (except 483.80 (i)(3)(ii)).

Within 60-days of Issuance of QSO 22-07-All

The facility must implement the following:

- All staff, prior to providing any care or services, must have
 - received all doses of a multi-dose COVID-19 vaccine, or
 - a one-dose COVID-19 vaccine, or
 - been granted a request for an exemption, or
 - been identified as having a temporarily delayed vaccination, and
- The facility must have developed and implemented policies and procedures for §483.80 (i)(3)(ii).

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Within 60 days of issuance of QSO 22-07-All, The facility must implement the following:

All staff, prior to providing any care or services, must have

received all doses of a multi-dose COVID-19 vaccine, or

a one-dose COVID-19 vaccine, or

been granted a request for an exemption, or

been identified as having a temporarily delayed vaccination, and

The facility must have developed and implemented policies and procedures for §483.80 (i)(3)(ii).

Exemptions from Staff Vaccination Requirements

- Facilities must have a process for staff to request an exemption from COVID-19 vaccination based on recognized clinical contraindications or applicable Federal laws addressing religious exemptions.
- · The process should:
 - identify how an exemption is requested;
 - identify to whom the request must be made;
 - include collection and evaluation of exemption requests; and
 - include secure documentation and tracking of exemption request information.

Note: Staff who are unable to furnish proper documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

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As required by the rule, facilities must have a process for staff to request an exemption from vaccination that is based on recognized clinical contraindications or applicable federal laws which address religious exemptions. The process should:

Identify how an exemption is requested, and to whom the request must be made;

Address the collection and evaluation of each exemption request, and include secure documentation and tracking of exemption request information. Staff who are unable to furnish proper documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Exemptions from Vaccination Requirements

Certain allergies or medical conditions may provide grounds for a medical exemption

- In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a
 previous dose or to a component of the COVID-19 vaccine, an immediate allergic reaction of
 any severity to a previous dose, or known allergy to a component of the vaccine, to be a
 contraindication to COVID-19 vaccination. See the CDC's <u>Summary Document for Interim</u>
 Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.
- Staff who requests a medical exemption from COVID-19 vaccination must provide documentation containing all of the required information.

Certain federal laws may provide grounds for a non-medical exemption

Requests for non-medical exemptions, such as a religious exemption in accordance with Title
VII, must be documented and evaluated in accordance with applicable federal law and each
facility's policies and procedures.

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Certain federal laws may provide grounds for a non-medical exemption

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with applicable federal law and each facility's policies and procedures. Surveyors will not evaluate the details of the non-medical exemption request, or the rationale for the facility's acceptance or denial of the request, rather only ensure there is a process for requesting such exemption.

Temporarily Delayed Vaccination

- In addition to medical contraindications, CDC recommends temporarily delaying administration of a COVID-19 vaccination due to clinical precautions and considerations such as:
 - o individuals with acute illness secondary to COVID-19 illness, or
 - o individuals who received monoclonal antibodies, or convalescent plasma for COVID-19 treatment.
- See the CDC's Summary Document for Interim Clinical Considerations for all clinical precautions. https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.odf
- Facilities must have a process to securely document and track the status of staff for whom vaccination is temporarily delayed.

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CDC recommends temporarily delaying administration of a COVID-19 vaccination due to clinical precautions and considerations such as:

individuals with acute illness secondary to COVID-19 illness, or

individuals who received monoclonal antibodies, or convalescent plasma for COVID-19 treatment.

For more information you can go to the CDC website listed on the slide.

Facilities must have a process to securely document and track the status of staff for whom vaccination is temporarily delayed.

Contingency Plans

Facilities are required to have contingency plans for staff who are not fully vaccinated and should:

- Include actions the facility will take when staff decline vaccination and do not qualify for an exemption, such as:
 - establishing a deadline for staff to receive a single-dose vaccine or the first dose of a multi-dose vaccine,
 - obtaining temporary vaccinated staff until permanent vaccinated staff can be hired,
 - o actively seeking vaccinated staff through advertising.
- Address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as implementing additional precautions.

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Facilities are required to have contingency plans for staff who are not fully vaccinated. These plans should:

Include actions that will be taken when staff decline vaccination and do not qualify for an exemption, such as:

- deadlines for staff to receive a single-dose vaccine or the first dose of a multi-dose vaccine,
- obtaining temporary vaccinated staff until permanent vaccinated staff can be hired,
- seeking vaccinated staff through advertising.

Contingency plans should address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as implementing additional precautions.

Contingency Plans

Review facility records and **interview staff** to confirm the facility has implemented their contingency plan, if needed, by:

- verifying the actions taken for any staff who indicated they would not get vaccinated and did not qualify for an exemption.
- asking when staff was given a deadline to receive the first dose of a vaccine? Confirm the date.
- identifying what actions were taken, if the deadline has passed.

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Surveyors should review records and **interview staff** to confirm the facility has implemented their contingency plan, if needed, by:

verifying the actions taken for staff who would not get vaccinated and did not qualify for an exemption.

asking when a deadline to receive the first dose of a vaccine was given? Confirm the date.

identify what actions were taken, if the deadline has passed.

Survey Process for Compliance

- Surveyors will investigate for compliance with these requirements as part of initial, standard recertification, and complaint surveys, beginning 30-days after the issuance of QSO 22-07-All.
- Updated survey tools include:
 - o Infection Prevention, Control & Immunizations Facility Task (IPC Task),
 - o LTC Procedure Guide,
 - o COVID-19 Focused Infection Control (FIC) Survey Protocol, and
 - o Entrance Conference Worksheets
- An optional COVID-19 Vaccination Matrix for Staff has also been developed for F888, which can be found in the Survey Resources folder.

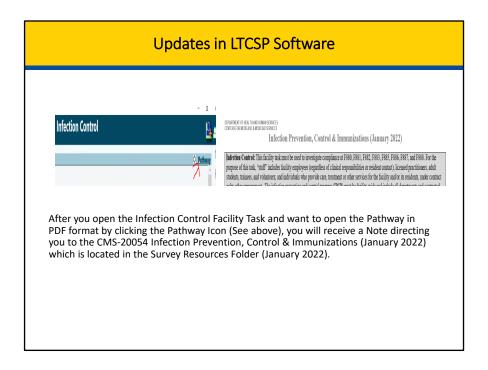
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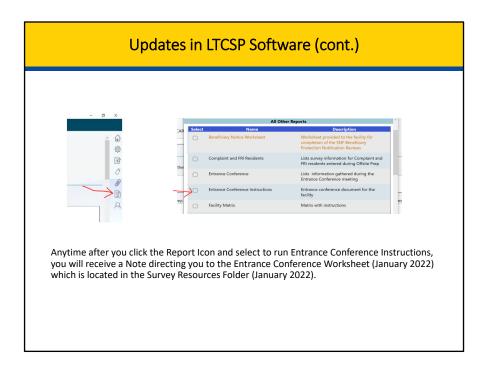
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The LTCSP Software has been updated to reflect the staff vaccination requirement.

For the Infection Control Facility Task, we updated the screen including the Critical Elements to make compliance determinations for this requirement. In the software, if you click on the Icon at the red arrow, you will Not see a pathway. Instead, there will be a Note directing you to retrieve it from the Survey Resource Folder (January 2022).



The Entrance Conference screen has also been updated.

Any time when you select to run the Entrance Conference Instructions by clicking the Report Icon in the LTCSP, you will Not see the Instructions. Instead, there will be a Note directing you to retrieve it from the Survey Resource Folder (January 2022).

Offsite Preparation

- Obtain the facility's staff COVID-19 vaccination data from NHSN.
 - NHSN staff vaccination data for each facility are accessible through a link provided in the IPC Task and on the CMS <u>COVID-19 Nursing Home Data</u> webpage.
 - The facility's vaccination rate is listed in the column titled, "Recent Percentage of Staff who are Fully Vaccinated."
- Record the percentage of staff from the column above in the IPC Task.

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As part of Offsite Preparation, surveyors will begin by comparing the facility's staff vaccination data provided to the surveyors with what is reported to NHSN. Instructions over the next several slides will describe this process. First, obtain the facility's staff COVID-19 vaccination data from NHSN. The data can be obtained through a link provided in the IPC Task and on the CMS COVID-19 Nursing Home Data webpage.

The facility's vaccination rate is listed in the column titled, "Recent Percentage of Staff who are Fully Vaccinated."

Record the percentage of staff from the column above in the IPC Task.

Entrance Conference

Request the following documentation:

- COVID-19 policies and procedures for staff vaccination;
- A numbered list of resident and staff COVID-19 cases over the last 4 weeks and indicate whether any resident cases resulted in hospitalization or death; and
- · A list of all staff and their vaccination status, including:
 - o the title, position, and assigned work area of each staff member, and
 - o the percent of staff vaccinated

Note: Facilities may use the COVID-19 Vaccination Matrix for Staff or provide their own list of all staff as long as all information requested by the surveyor is included.

Surveyors may use the Staff Matrix information to determine how unvaccinated staff are assigned, to determine if additional precautions have been implemented to prevent COVID-19 transmission.

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During the Entrance conference the surveyor **Requests** the following:

policies and procedures for staff vaccination;

A numbered list of resident and staff COVID-19 cases over the last 4 weeks, indicating whether any residents were hospitalized or expired; **and**

A list of all staff and their vaccination status, including:

- o the title, position, and assigned work area of each staff member, and
- the percent of staff vaccinated

Facilities may use the COVID-19 Vaccination Matrix for Staff or provide their own list of all staff as long as all information requested by the surveyor is included.

Investigative Procedures

Compare the NHSN data retrieved during offsite prep to the staff vaccination information provided by the facility. The percent of staff vaccinated obtained from NHSN and provided by the facility should be reasonably consistent, but may not be exactly the same due to reporting lag time.

- If there is a 10% or less difference between the NHSN data and data obtained onsite, no further investigation is required.
- If there is a 10% or greater difference, interview facility staff and review the documentation to determine which source is incorrect and the explanation for the discrepancy.

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Once onsite, after the facility has provided the staff vaccination status, the survey team

offsite prep to the staff vaccination information provided by the facility. The percent of staff vaccinated obtained from NHSN and provided by the facility should be reasonably consistent, but may not be exactly the same due to reporting lag time.

If there is a 10% or less difference between the NHSN data and data obtained onsite, no further investigation is required. If there is a 10% or greater difference, determine which source is incorrect and the explanation for the discrepancy.

Investigative Procedures

- If it is determined the information presented by the facility is incorrect and NHSN is correct, or both sources are incorrect, this likely demonstrates the facility's failure to have a process for tracking and securely documenting the COVID-19 vaccination status for all staff, consider citing F888.
- If it is determined the information reported to NHSN is incorrect and the information reviewed onsite is correct, the surveyor should instruct the facility to immediately correct the NHSN information.
- If the surveyor identifies that a data field is blank, instruct facilities to obtain additional information on submitting data to NHSN by emailing NH_COVID_Data@cms.hhs.gov.

Note: The determination that one source is incorrect does not automatically infer that the other source is correct.

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If the facility information is incorrect and NHSN is correct, or both sources are incorrect, it is likely the facility has failed to have a process for tracking and securely documenting, consider citing F888.

If the information reported to NHSN is incorrect, and information reviewed onsite is correct, instruct the facility to immediately correct the NHSN information.

If the surveyor identifies that a data field is blank, instruct facilities to obtain additional information on submitting data to NHSN by emailing NH_COVID_Data@cms.hhs.gov.

Vaccination Enforcement

- CMS expects all staff to have received the appropriate number of doses by the timeframes specified in QSO 22-07-All unless exempted as required by law.
- Facility staff vaccination rates under 100% constitute non-compliance under the rule.
- Non-compliance does not necessarily lead to termination and facilities will generally be given opportunities to return to compliance.

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CMS expects all staff to have received the appropriate number of doses by the timeframes specified in QSO 22-07-All unless exempted as required by law.

Facility staff vaccination rates under 100% constitute non-compliance under the rule.

Non-compliance does not necessarily lead to termination and facilities will generally be given opportunities to return to compliance.

Temporary Enforcement Thresholds - 30-days

For surveys conducted days 30 - 59, following the issuance of QSO 22-07-All.

The facility is **compliant** if it demonstrates:

- all policies and procedures are developed and implemented, except §483.30(i)(3)(ii), and
- 100% of staff have received at least one dose of COVID-19 vaccine, have a
 pending request for or have been granted an exemption, or have been identified
 as having a temporarily delayed vaccination.

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Let's talk about surveys conducted from day 30 through day 59 following issuance of QSO-22-07-All. The facility is considered compliant if it demonstrates that all policies and procedures are developed and implemented, and, that 100% of staff have received at least one dose of vaccine, or have a pending request for, or have been granted an exemption, or has a temporarily delayed vaccination.

Temporary Enforcement Thresholds - 30-days(cont.)

For surveys conducted days 30 - 59 (cont.)

If a facility demonstrates **80% - 99%** of staff received at least one dose of a COVID-19 vaccine, have a pending request for or have been granted an exemption, or have a temporarily delayed vaccination, the **facility is non-compliant with the 100% vaccination requirement.**

- · The facility will be cited using tag F888 on the CMS-2567.
- If the facility is above 80% and has a plan has a plan to achieve a 100% staff vaccination rate within 60 days they would not be subject to an enforcement action.

States should work with their CMS location for cases that exceed the 80% threshold, yet pose a threat to resident health and safety.

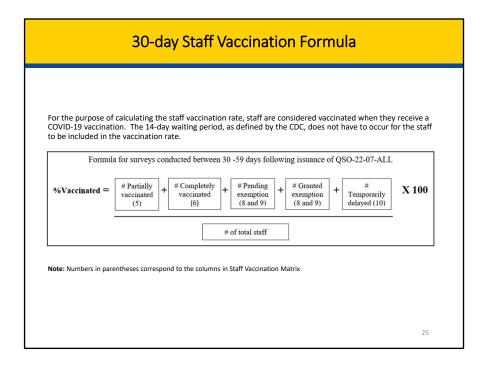
If a facility demonstrates less than 80% of staff received at least one dose of COVID-19 vaccine, have a pending request for or have been granted an exemption, or have a temporarily delayed vaccination, the facility is non-compliant with the 100% vaccination requirement.

• The facility will be cited at tag F888 and could be subject to additional enforcement actions. **Note:** Use the Phase 1 staff vaccination formula to calculate vaccination rates days 30-59.

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As we continue discussing surveys at day 30 through 59 following issuance of the memo, facilities that have less than 100% of staff who have received at least one dose of a vaccine, or is pending or has been granted an exemption, or has a temporary delay, the facility is noncompliant and will be cited using F888. If the facility is above 80% and has a plan to achieve 100% vaccination rate within 60 days, they would not be subject to an enforcement action. However, States should work with their CMS location for cases that exceed the 80% threshold, yet pose a threat to resident health and safety.

Facilities with less than 80% of staff who have received at least one dose of vaccine, or have a pending request for, or have been granted an exemption, or a temporary delayed vaccination, the facility is noncompliant and will be cited at F888 and could be subject to additional enforcement actions.



This slide shows the 30 day staff vaccination formula. When calculating the staff vaccination rate, staff are considered vaccinated when they receive a COVID-19 vaccination. The 14 day waiting period does not have to occur to include the staff in the vaccination rate.

30-days Enforcement Threshold - Example #1

The Facility employs 98 staff. 55 staff received all doses of a multi-dose vaccine, 39 received one dose of a multi-dose vaccine, 1 has a pending medical exemption request, and 3 have pending requests for religious exemptions.

- 55 + 39 + 1 + 3 = 98 98 ÷ 98 = 1 x 100 = **100% of staff** are vaccinated, have a granted/pending exemption, or a temporary delay.
- The Facility is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to their staff vaccination rate.
- The Facility may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

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Here is an example. The Facility employs 98 staff. 55 staff received all doses of a multi-dose vaccine, 39 received one dose of a multi-dose vaccine, 1 has a pending medical exemption request, and 3 have pending requests for religious exemptions.

55 + 39 + 1 + 3 = 98 $98 \div 98 = 1 \times 100 = 100\%$ of staff are vaccinated, or have a granted or pending exemption.

The Facility is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to their staff vaccination rate.

The Facility may still be cited if non-compliance with the other requirements is identified (for example policies and procedures).

30-days Enforcement Threshold - Example #2

The Facility employs 165 staff. 122 staff received all doses of a multi-dose vaccine, 17 received one dose of a multi-dose vaccine, 1 has a pending medical exemption request, 1 has a temporary delay, 3 staff have not received any doses of COVID-19 vaccine and do not have a pending request for an exemption or identified as having a temporary delay.

- 122 + 17 + 1 + 1 = 141
 141 ÷ 165 = 0.854 x 100 = 85.4 or 85% of staff are vaccinated, have a granted/pending exemption, or have a temporary delay.
- The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.
- The facility may also be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

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Let's look at another example. The Facility employs 165 staff. 122 staff received all doses of a multi-dose vaccine, 17 received only one dose of a multi-dose vaccine, 1 has a pending medical exemption request, 1 has a temporary delay, 3 staff have not received any doses of COVID-19 vaccine and do not have a pending request for an exemption or have been identified as having a temporary delay.

122 + 17 + 1 + 1 = 141 $141 \div 165 = 0.854 \times 100 = 85.4$ or **85% of staff** are vaccinated, or have a granted/pending exemption, or have a temporary delay.

The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.

The facility may also be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

30-days Enforcement Threshold - Example #3

The Facility employs 100 staff. 58 have received all doses of a multi-dose vaccine, 5 have been granted medical exemptions, 5 have pending religious exemptions, 10 have a temporary delay, and 10 have not received any doses of COVID-19 vaccine and do not have a pending request for an exemption.

- 58 + 5 + 5 + 10 = 78 $78 \div 100 = 0.78 \times 100 = 78\%$ of staff are vaccinated, have a granted/pending exemption, or have a temporary delay.
- The Facility is non-compliant with the 100% vaccination requirement and will be cited at F888 and could be subject to additional enforcement actions depending on the severity of the deficiency.

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Here is one more example. The Facility employs 100 staff. 58 have received all doses of a multi-dose vaccine, 5 have been granted medical exemptions, 5 have pending religious exemptions, 10 have a temporary delay, and 10 have not received any doses of COVID-19 vaccine and do not have a pending request for an exemption.

58 + 5 + 5 + 10 = 78 $78 \div 100 = 0.78 \times 100 = 78\%$ of staff are vaccinated, or have a granted or pending exemption, or have a temporary delay.

The Facility is non-compliant with the 100% vaccination requirement and will be cited at F888 and could be subject to additional enforcement actions depending on the severity of the deficiency.

Temporary Enforcement Thresholds - 60-days

For surveys conducted days 60 – 89, following the issuance of QSO 22-07-All.

The facility is **compliant** if it demonstrates:

- all policies and procedures have been developed and implemented, and
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., a single-dose vaccine or all doses of a multiple vaccine series) or have been granted an exemption, or identified as having a temporary delay for vaccination.

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Let's talk about enforcement thresholds for surveys conducted between days 60 and 89 following issuance of QSO-22-07-All. Again, facilities are expected to be 100% compliant with the requirements. A facility is compliant if all policies and procedures have been developed and implemented, and 100% of all staff have received the necessary doses to complete the primary vaccine series, or have been granted an exemption, or have been identified as having a temporary delay for vaccination.

Temporary Enforcement Thresholds - 60-days (cont.)

For surveys conducted days 60 - 89 (cont.)

If a facility demonstrates 90% - 99% of staff have received a single-dose vaccine, all doses of a multi-dose vaccine, or have been granted an exemption, or identified as having a temporary delay, the facility is non-compliant with the 100% vaccination requirement.

- The facility will be cited using tag F888 on the CMS-2567
- If the facility has a plan has a plan to achieve a 100% staff vaccination rate within 30 days they
 would not be subject to an enforcement action.

States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to resident health and safety.

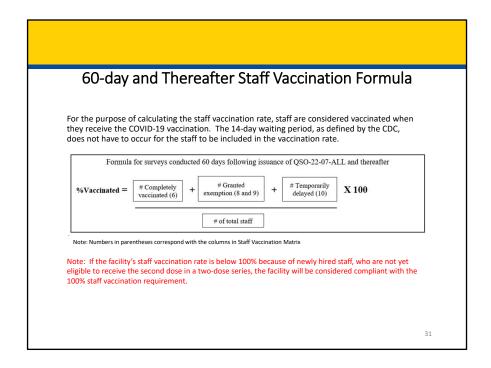
If a facility demonstrates less than 90% of staff have received a single-dose vaccine, all doses of a multidose vaccine, have been granted an exemption, or identified as having a temporary delay, the facility is non-compliant with the 100% vaccination requirement.

• The facility will be cited using tag F888 and could be subject to additional enforcement actions. **Note:** Use the Phase 2 staff vaccination formula to calculate vaccination rates days 60 and beyond.

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For surveys at day 60 through 89, following issuance of the memo, facilities that have less than 100% of staff who have completed their primary vaccination series, which means a single dose vaccine, or all doses of a multiple dose vaccine series, or has been granted an exemption, or a temporary delay, the facility is noncompliant and will be cited using F888. If the facility is above 90% **and** has a plan to achieve 100% vaccination rate within 30 days, they would not be subject to an enforcement action. However, States should work with their CMS location for cases that exceed the 90% threshold, yet pose a threat to resident health and safety.

Facilities with less than 90% of staff having completed their primary vaccination series, or have been granted an exemption, or a temporary delayed vaccination, the facility is noncompliant and will be cited at F888 and could be subject to additional enforcement actions.



This slide shows the 60 day and thereafter staff vaccination formula. Surveyors should note that for purposes of calculating the staff vaccination rate, staff are considered vaccinated when they receive a COVID-19 vaccination. The 14 day waiting period does not have to occur to include the staff in the vaccination rate. Please note for surveys at day 60 and beyond, if the facility's staff vaccination rate is below 100% because of newly hired staff, who are not yet eligible to receive the second dose in a two-dose series, the facility will be considered compliant with the 100% staff vaccination requirement.

60-days Enforcement Threshold - Example #1

The Facility employs 211 staff. 107 staff received all doses of a multi-dose vaccine, 99 staff received a single-dose vaccine, 3 have been granted medical exemptions, and 2 have a temporary delay.

- 107 + 99 + 3 + 2 = 211 $211 \div 211 = 1 \times 100 = 100\%$ of staff are vaccinated, have a granted exemption, or have a temporary delay.
- The Facility is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to staff vaccination rate.
- The Facility may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

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On this slide we have an example of this enforcement threshold. The Facility employs 211 staff. 107 staff received all doses of a multi-dose vaccine, 99 staff received a single-dose vaccine, 3 have been granted medical exemptions, and 2 have a temporary delay.

107 + 99 + 3 + 2 = 211 $211 \div 211 = 1 \times 100 = 100\%$ of staff are vaccinated, have a granted exemption, or have a temporary delay.

The Facility is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to staff vaccination rate.

The Facility may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

60-days Enforcement Threshold - Example #2

The Facility employs 38 staff. 13 staff received all doses of a multi-dose vaccine, 17 received a single-dose vaccine, 5 have a temporary delay, and 3 have not received any doses of COVID-19 vaccine and have not been granted an exemption.

- 13 + 17 + 5 = 35 $35 \div 38 = 0.921 \times 100 = 92.1$ or **92% of staff** are vaccinated, have a granted exemption, or a temporary delay.
- The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.
- The Facility may also be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

3

Lets' look at another example. The Facility employs 38 staff. 13 staff received all doses of a multi-dose vaccine, 17 received a single-dose vaccine, 5 have a temporary delay, and 3 have not received any doses of COVID-19 vaccine and have not been granted an exemption.

13 + 17 + 5 = 35 $35 \div 38 = 0.921 \times 100 = 92.1$ or **92% of staff** are vaccinated, have a granted exemption, or a temporary delay.

The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.

The Facility may also be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

60-days Enforcement Threshold - Example #3

The Facility employs 83 staff. 30 staff received all doses of a multi-dose vaccine, 35 received a single-dose vaccine, 2 have a temporary delay and 16 have not received any doses of COVID-19 vaccine and do not have an exemption.

- 30 + 35 + 2 = 67 67 ÷ 83 = 0.807 x 100 = 80.7 or **81% of staff** are vaccinated, have a granted exemption, or have a temporary delay.
- The Facility is non-compliant with the 100% vaccination requirement and will be cited at F888 and could be subject to enforcement actions depending on the severity of the deficiency.

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Here is one more example of the 60day threshold. The Facility employs 83 staff. 30 staff received all doses of a multi-dose vaccine, 35 received a single-dose vaccine, 2 have a temporary delay and 16 have not received any doses of COVID-19 vaccine and do not have an exemption.

30 + 35 + 2 = 67 $67 \div 83 = 0.807 \times 100 = 80.7$ or **81% of staff** are vaccinated, have a granted exemption, or have a temporary delay.

The Facility is non-compliant with the 100% vaccination requirement and will be cited at F888 and could be subject to enforcement actions depending on the severity of the deficiency.

Temporary Enforcement Thresholds - 90-days

For surveys conducted on or after day 90, following the issuance of QSO 22-07-All.

The facility is **compliant** if it demonstrates:

- All policies and procedures have been developed and implemented, and
- 100% of staff have received a single-dose vaccine, all doses of a multi-dose vaccine, have been granted an exemption, or have a temporary delay.

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And finally, the last enforcement threshold occurs 90 days following issuance of QSO-22-07-All. Facilities are expected to be 100% compliant with the requirements. A facility is considered compliant if it demonstrates that all policies and procedures have been developed and implemented, and 100% of all staff have received the necessary doses to complete the primary vaccine series, which means a single dose vaccine, or all doses of a multiple dose vaccine series, or have been granted an exemption, or have been identified as having a temporary delay for vaccination.

90-days Enforcement Threshold - Example #1

The Facility employs 304 staff. 133 staff received all doses of a multi-dose vaccine, 167 received a single-dose vaccine, 1 has been granted a medical exemption, and 3 have been granted a non-medical exemption.

- 133 + 167 + 1 + 3 = 304 304 ÷ 304 = 1 x 100 = **100% of staff** are vaccinated, have a granted exemption, or have a temporary delay.
- The Facility is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to staff vaccination rate.
- The Facility may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

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Here is an example of calculating the percent of staff vaccinated at 90 days: The Facility employs 304 staff. 133 staff received all doses of a multi-dose vaccine, 167 received a single-dose vaccine, 1 has been granted a medical exemption, and 3 have been granted a non-medical exemption.

133 + 167 + 1 + 3 = 304 $304 \div 304 = 1 \times 100 = 100\%$ of staff are vaccinated, have a granted exemption, or have a temporary delay.

The Facility is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to staff vaccination rate.

The Facility may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

90-days Enforcement Threshold - Example #2

The Facility employs 156 staff. 119 staff received all doses of a multi-dose vaccine, 28 received a single-dose vaccine, and 9 received one dose of a multi-dose vaccine.

- 119 + 28 = 147 $147 \div 156 = 0.942 \times 100 = 94.2$ or **94% of staff** vaccinated, have a granted exemption, or have a temporary delay.
- The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.
- The facility may also be subject to enforcement actions.

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Another example of calculating the percentage of staff at 90 days: The Facility employs 156 staff. 119 staff received all doses of a multi-dose vaccine, 28 received a single-dose vaccine, and 9 received one dose of a multi-dose vaccine.

119 + 28 = 147 $147 \div 156 = 0.942 \times 100 = 94.2$ or **94% of staff** vaccinated, have a granted exemption, or have a temporary delay.

The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.

The facility may also be subject to enforcement actions.

Investigative Procedures

- Review the facility's policies and procedures for staff COVID-19 vaccination.
- Use the Infection Prevention, Control & Immunizations Facility Task, along with the interpretive guidance, to investigate and determine if the facility meets the requirements for COVID-19 vaccination of staff.
- Focus investigations on staff that provide services in the facility on a regular basis (e.g., weekly).

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Now we are going to switch gears and talk about how surveyors will investigate for these requirements. Surveyors will review the facility's policies and procedures. You will use the infection prevention, control and Immunizations facility task and interpretive guidance determine if the facility meets the requirements. Investigations should be focused on staff that provide services in the facility on a regular basis, for example weekly.

Sample Selection

Select 8 staff from the staff matrix or facility list:

- · 2 vaccinated staff
 - · One certified nurse aide (CNA)
 - One who provides care or services under contract or other arrangement (e.g., hospice or dialysis staff, therapists, mental health professionals, licensed practitioners)
- 6 unvaccinated staff (if any exist)
 - Three (two CNAs, if available) who do not have an exemption or temporary delay;
 - One with a non-medical exemption, such as religious exemption;
 - One with a medical exemption (if there are more than 2 staff with medical exemptions review 50% of the staff from this category);
 - One whose primary vaccination series has been temporarily delayed

Note: If no staff meet one of the unvaccinated criteria, do not increase the sample size for another area. If the surveyor identifies any staff who are not vaccinated, were not granted an exemption or have a temporary delay, and weren't identified as such on the staff matrix, add the individual(s) to the sample.

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The Sample selection will include 8 staff. 2 should be vaccinated staff, 1 of which is a certified nurse aide or CNA, and another staff who provides care or services under contract or other arrangement. The remaining 6 should be unvaccinated staff if any exist. Of these, 3 (2 who are CNAs) should not have an exemption or temporary delay, 1 with a non-medical exemption, one with a medical exemption, however, please note, if there are more than 2 staff with medical exemptions, review 50% of the staff from this category. And lastly, select 1 whose primary vaccination series has been temporarily delayed.

If no staff meet one of the unvaccinated criteria, do not increase the sample size for another area to make the total number of unvaccinated staff equal 6. Additionally, if the surveyor identifies any staff who are not vaccinated, were not granted an exemption or have a temporary delay, and weren't identified as such on the staff matrix, add the individual(s) to the sample.

Staff Observation & Interview

Observe and interview sampled unvaccinated staff to determine if additional precautions are in place to help prevent the spread of COVID-19.

- Are unvaccinated staff using additional precautions, including universal source control (use a NIOSH-approved N95 or equivalent or higher-level respirator for source control) and physical distancing at all times while in the facility?
- · If reassigned, when were you reassigned duties?
- Are you being tested for COVID-19? If so, how often?
- Determine whether other additional precautions are in place to mitigate the transmission of COVID-19.

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Surveyors should observe and interview sampled unvaccinated staff to determine if additional precautions are in place. Consider the following: Are unvaccinated staff using additional precautions, including universal source control (use a NIOSH-approved N95 or equivalent or higher-level respirator for source control) and physical distancing at all times while in the facility?

If reassigned, when were staff reassigned duties?

Are unvaccinated staff being tested for COVID-19? If so, how often?

Determine whether other additional precautions are in place to mitigate the transmission of COVID-19.

Record Review of Vaccinated Staff

Review documentation to verify staff vaccination status

- Documentation must demonstrate administration of:
 - o a single-dose COVID-19 vaccine, OR
 - o all required doses for a multi-dose vaccination series, AND
 - o any booster doses received

Note: See requirements at \$483.80(d)(3) in F887 for verification and maintenance of documentation related to staff COVID-19 vaccination.

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In addition to Observation and interview, surveyors must review documentation to verify staff vaccination status. Documentation must demonstrate administration of a single dose vaccine, or all required doses for a multi-dose vaccination series, and any booster doses received. Additional information can be found at F887 for verification and maintenance of documentation related to staff vaccination.

Record Review for Medical Exemption Requests

Review documentation for staff who requested a medical exemption to determine if the requests are secure, tracked and contains:

- which COVID-19 vaccine is clinically contraindicated;
- the recognized clinical reason for the contraindication;
- a statement recommending the staff member be exempted from the COVID-19 vaccination requirement; and
- a signature and date by a licensed practitioner, who is not the individual requesting the exemption.

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Surveyors will review documentation to determine if medical exemption requests are secure, tracked and contain:

which COVID-19 vaccine is clinically contraindicated;

the recognized clinical reason for the contraindication;

a statement recommending the staff be exempted from vaccination requirement; and

a signature and date by a licensed practitioner, who is not the individual requesting the exemption.

Record Review for Non-Medical Exemptions

Review documentation for staff who requested a non-medical exemption to determine if the requests are secure and tracked.

Interview staff to determine the following:

- What is the process to request a non-medical exemption, such as a religious exemption?
- How are staff informed about the process to request a nonmedical exemption?

Do not evaluate the details of the request for a non-medical (e.g., religious) exemption **or** the rationale for the facility's acceptance or denial of the request.

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Surveyors will review non-medical exemption documentation to determine if the requests are secure and tracked, and to determine what the process is to request a non-medical exemption, and how staff are informed about the process to request a non-medical exemption. Please note, surveyors do not evaluate the details of the request for a non-medical (e.g., religious) exemption **or** the rationale for the facility's acceptance or denial of the request.

Record Review for Temporarily Delayed Vaccination

Review documentation for staff for whom COVID-19 vaccination is temporarily delayed to determine if the documentation is secure, tracked and includes the following:

- o the reason for delaying COVID-19 vaccination;
- o how long the delay is expected; and
- o a plan for vaccination when the delay is over.
- If during the documentation review, the surveyor determines the timeframe for the temporary delay has passed, evaluate whether the staff member was vaccinated.

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For staff whose vaccination has been temporarily delayed, surveyors will determine if the documentation is secure, tracked and includes:

- o the reason for delaying COVID-19 vaccination;
- how long the delay is expected; and
- o a plan for vaccination when the delay is over.

If the timeframe for the temporary delay has passed, evaluate whether the staff member was vaccinated.

Unvaccinated Staff Who <u>Do Not</u> Have an Exemption or Temporary Delay

Interview staff and **Review** documentation for unvaccinated staff without an exemption or temporarily delayed vaccination:

- Are you scheduled to receive a COVID-19 vaccine? If so, confirm it is scheduled.
- If the staff isn't scheduled to receive a vaccine: Did you request an exemption?
- When did the facility become aware staff did not have an exemption or a reason for temporary delay?
- What actions did the facility take to educate and offer COVID-19 vaccines to staff?
- What actions did the facility take when staff indicated that they will not get vaccinated and do not qualify for an exemption?

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Surveyors should interview staff and review documentation for unvaccinated staff without an exemption or temporarily delayed vaccination to determine:

If the staff is scheduled to receive a COVID-19 vaccine? If so, confirm it is scheduled.

If the staff isn't scheduled to receive a vaccine: Did the staff request an exemption?

When did the facility become aware staff did not have an exemption or a reason for temporary delay?

What actions did the facility take to educate and offer COVID-19 vaccines to staff?

What actions did the facility take when staff indicated that they will not get vaccinated and do not qualify for an exemption?

Compliance Determination for F888

- After investigating using the Infection Prevention, Control and Immunizations
 Facility Task, determine compliance with the requirements using the critical
 element questions.
- If the facility is non-compliant with the 100% vaccination requirement and/or has not developed and implemented the required policies and procedures, cite F888.
- The level of severity will be cited based on the level of harm, or likelihood of harm for residents.

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Compliance determination for F888.

Long-term care surveyors will use the Infection Prevention, Control and Immunizations Facility Task, to determine compliance with the requirements using the critical element questions.

If the facility is non-compliant with the 100% vaccination requirement and/or has not developed and implemented the required policies and procedures, cite F888.

The severity level for noncompliance at F888 is based on the level of harm, or likelihood of harm for residents. For example, facilities with a high percentage of unvaccinated staff, several COVID-19 infections, and gaps in their policy and procedures, represent a higher risk of harm to residents. Therefore, these facilities would be cited at a higher level of severity than facilities with few unvaccinated staff, no COVID-19 infections, and compliant policy and procedures.

Good Faith Effort

Surveyors and CMS may use discretion to lower the scope and severity of a citation and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the scope, severity, and/or enforcement is adjusted):

- If the facility has limited or no access to vaccines and has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies) and/or
- If the facility provides evidence they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

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CMS may use discretion to lower scope and severity of a citation and/or enforcement action if the following occurred prior to the survey:

The facility has limited or no access to vaccines, and/or

The facility provides evidence that they have taken aggressive steps to have all staff vaccinated.

Citing Non-Compliance – Level 4 Immediate Jeopardy

- · Noncompliance resulting in serious harm or death:
 - Did not meet the requirement of staff vaccinated or has no policies and procedures developed or implemented; and
 - 3 or more resident infections in the last 4 weeks resulting in at least one resident experiencing hospitalization (i.e, serious harm) or death.

OR

- Noncompliance resulting in a likelihood for serious harm or death:
 - Did not meet the requirement of staff vaccinated; and
 - 3 or more resident infections in the last 4 weeks that did not result in serious harm or death; and
 - One of the following:
 - Any observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE so F880 would also be cited); or
 1 or more components of the policies and procedures was not developed or implemented.

OR

More than 40% staff are unvaccinated and there is evidence of a lack of effort to increase staff vaccination rates.

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Surveyors will assign severity based on the criteria listed in Attachment A. Let's look at Severity level 4, or Immediate Jeopardy. Noncompliance resulting in serious harm or death exists when the facility:

Did not meet the required percent of staff vaccinated, or has no policies or procedures developed or implemented, AND

3 or more resident COVID-19 infections have occurred in the last 4 weeks with at least one resident being hospitalized or dying.

Noncompliance resulting in a likelihood for serious harm or death exists when:

Did not meet the required percent of staff vaccinated, or has no policies or procedures developed or implemented, AND

3 or more resident COVID-19 infections have occurred in the last 4 weeks which did not result in serious harm or death, AND one of the following:

Any observations on noncompliant infection control practices, or 1 or more components of the policies and procedures was not developed or implemented. OR

More than 40% of staff are unvaccinated and a lack of effort to increase staff vaccination rates.

Citing Non-Compliance – Level 3

Citing Level 3: Actual Harm that is not Immediate Jeopardy

- · Did not meet the requirement of staff vaccinated; and
- 3 or more resident infections in the last 4 weeks which did not result in hospitalization (i.e., serious harm) or death, or the likelihood for IJ for one or more residents; and
- 1 or more components of the policies and procedures were not developed and implemented.

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Let's talk about Severity Level 3 – Actual Harm that is not Immediate Jeopardy

Actual Harm exists when a facility did not meet the requirement of staff vaccinated, AND

3 or more resident infections in the last 4 weeks which did not result in hospitalization (i.e., serious harm) or death, or the likelihood for IJ for one or more residents; and

1 or more components of the policies and procedures were not developed and implemented.

Citing Non-Compliance – Level 2

Citing Level 2: No actual harm with potential for more than minimal harm that is not immediate jeopardy

- Did not meet the requirement of staff vaccinated; and
- · No resident infections

OR

- · Did not meet the requirement of staff vaccinated; and
- 1 or more components of the policies and procedures were not developed and implemented

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Severity Level 2, Potential for more than minimal harm exists when a facility Did not meet the requirement of staff vaccinated; <u>and</u>
No resident infections

OR

Did not meet the requirement of staff vaccinated; and

1 or more components of the policies and procedures were not developed and implemented

Citing Non-Compliance – Level 1

Citing Level 1: No actual harm with potential for minimal harm:

- Met the requirement of staff vaccinated; and
- 1 or more components of the policies and procedures were not developed and implemented (cite as widespread ("C").

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Severity level 1 – potential for minimal harm exists when a facility Met the requirement of staff vaccinated; and

1 or more components of the policies and procedures were not developed and implemented (cite as widespread ("C").

Determining Scope

Scope is based on the percent of staff vaccinated, therefore, the scope will be based on the following criteria:

- Isolated: 1% or more, but less than 25% of staff are unvaccinated (76% – 99% of staff are vaccinated).
- Pattern: 25% or more, but less than 40% of staff are unvaccinated (61% – 75% of staff are vaccinated).
- Widespread: 40% or more of staff are unvaccinated (0% 60% of staff are vaccinated), OR

 And the staff are vaccinated to the staff are vaccinated to the staff are vaccinated to the staff are unvaccinated to the sta

1 or more components of the policies and Procedures were not developed and implemented.

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Scope is based on the percent of staff vaccinated. Scope is isolated when 1% or more, but less than 25% of staff are unvaccinated. Scope is a pattern when 25% or more, but less than 40% of staff are vaccinated, and scope is widespread when 40% or more of staff are unvaccinated, or 1 or more components of the policies or procedures were not developed or implemented.

Plan of Correction

To qualify for substantial compliance and clear the citation:

- The facility has met the requirement of staff vaccinated (either by staff obtaining additional doses or replacing unvaccinated staff with vaccinated staff); or
- The combined number of staff that are vaccinated (have received a single-dose vaccine or all doses of a multiple vaccine series) or have received at least one dose of a multiple dose vaccine series meet the expected minimum threshold of staff vaccinated.
 - Staff who have received at least one dose of a multiple vaccine series must also have their second dose scheduled.

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To qualify for substantial compliance and clear the citation:

The facility has met the requirement of staff vaccinated or

The combined number of staff that are vaccinated or have received at least one dose of a multiple dose vaccine series meet the expected minimum threshold of staff vaccinated.

 Staff who have received at least one dose of a multiple vaccine series must also have their second dose scheduled.

Plan of Correction

To qualify for substantial compliance but citation remains at level 1("C")

 The facility has not met the requirement of staff vaccinated, but has provided evidence that some of the unvaccinated staff have obtained their first dose, and other unvaccinated staff are scheduled for their first dose.

For example, the citation at Level 1 would continue if there is evidence that 50% of staff who were identified as unvaccinated have received one dose of a multiple vaccine series with their second dose scheduled or are scheduled to receive a single-dose vaccine series.

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To qualify for substantial compliance but citation remains at level 1 or a scope and severity of C:

The facility has not met the requirement of staff vaccinated, but has evidence that some of the unvaccinated staff have obtained their first dose, **and** other unvaccinated staff are scheduled for their first dose.

For example, the citation at Level 1 would continue if there is evidence that 50% of staff who were identified as unvaccinated have received one dose of a multiple vaccine series with their second dose scheduled or are scheduled to receive a single-dose vaccine series.

Plan of Correction

Components of POC and/or actions required for IJ removal:

Plans of correction or Immediate Jeopardy removal plans for non-compliance at F888 should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures;
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine; and
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

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Plans of correction should include:

Correction of any gaps in policies and procedures;

Implementation of the contingency plan, including a deadline for each unvaccinated staff to get first dose of vaccine,

Implementation of additional precautions.

Resources & Contact Information

- The updated associated survey documents, may be found under the "<u>Survey Resources</u>" link, in the Downloads section, of the CMS Nursing Homes website.
- The updated documents will also be added to the Long-Term Care Survey Process software application.
- For questions regarding LTC requirements, email: DNH_TriageTeam@cms.hhs.gov.

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Updated survey documents, may be found under the "<u>Survey Resources</u>" link, in the Downloads section, of the CMS Nursing Homes website.

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